Salt Lake County Vivitrol MAT Program Data Submitted to the Office of the Legislative Fiscal Analyst

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1. Intent Language—2017 Legislative Session

The Legislature intends the Department of Human Services provide to the Office of the Legislative Fiscal Analyst no later than August 15, 2017 the following information for the Medication Assisted Treatment Pilot Program: 1) cost per client, 2) changes in employment, housing, education, and income among clients, 3) the number of new charge bookings among clients, 4) measures of cost-effectiveness, 5) options for reducing the cost of treatment, including obtaining naltrexone from compounding pharmacies, and 6) options for continued funding beyond the current one-time funding, if the pilot shows positive outcome measures.

LFA notes:

- Individuals must abstain from opioid use for a minimum of 7-10 days before starting Vivitrol.
- Injections are given monthly by a healthcare professional.
- Vivitrol can treat opioid and alcohol dependency.
- Treatment reduces opioid tolerance and can therefore increase the risk of overdose. https://www.vivitrol.com/content/pdfs/prescribing-information.pdf

2. Cost Per Client Data

Vivitrol Program July 2015-June 2017		
Overall Spend	\$665,575.00	
Clients with 1+ Injection	284	
Cost Per Client	\$2,343.57	
Total Injections	1,085	
Average Injections Per Client	3.8	
Cost Per Injection*	\$613.43	

^{*}Cost per Injection can be as high as \$1,050, but because of the Patient Assistance Plan, Alkermes donating injections, the reduced FQHC cost at Midtown Community Health Center, and Medicaid coverage, average cost has been greatly reduced.

Overall spend: This includes the original \$500k (\$250k given to SLCo at inception, with another \$250k coming over by the end of our fiscal year from the Department of Corrections because they did not get their Vivitrol program going), as well as approximately \$166k from the county's \$250k appropriation in 2016.

Clients with 1+ injection: Clients are recommended 13 injections. 6 total clients have gone 13 or more, and 22 have gone 10 or more. 11 of these 22 are currently enrolled in the program, eligible to continue receiving injections. The overall recommendation does not vary, but some clients are not appropriate to continue. Some clients are recommended to discontinue participation for reasons varying from pregnancy and liver functioning, to continued use.

Cost per injection: For the Salt Lake County program, this figure includes county funding, patient assistance, Alkermes-donated, and a small number of Medicaid-covered injections. The total number of injections are tracked. Then the total cost is averaged out per injection. Some are \$0, while on the high end, they can cost over \$1k. The 613.43 is simply the total spent (at the time of data cut) divided by the total number of administered injections through the county program (at time of data cut).

3. National Outcomes Measures (NOMs) Indicators (Employment, Housing, Education, Income)

Data available at: http://integratedrecovery.org/wp-content/uploads/2010/08/SAMHSA-National-Outcome-Measures.pdf

Dataset: Every client in this particular dataset (n=140) will have at least had one full year since admission. This is a subset of the entire program dataset. It accounts for all the clients who have had at least one year since they began the program. The dataset was modeled around recidivism. We pulled only clients who had data available at a minimum of one year post admission. Others, which we will continue to see about data collection for, come from the Department of Corrections, outside of our Electronic Health Record.

Changes in Employment

Employment Description (n=140) ¹	Admission of Earliest Record	Most Recent Record/Discharge	Percent Change
Full and Part Time/ Student	35	64	83%
Unemployed	70	64	-9%
Disabled or Other Not in Labor Force	35	12	-66%

¹ Data not available for clients without treatment records collected in the Salt Lake County dataset (clients coming from the Department of Corrections Treatment Resource Centers or out-of-network providers, Medicaid and self-pay clients, or those who transition to the Patient Assistance Plan (PAP) and wish to not continue case management with the Salt Lake County Vivitrol Program).

Changes in Housing

Housing Description (n=140) ²	Admission of Earliest Record	Most Recent Record/Discharge	Percent Change
Street or Homeless Shelter/Jail or Correctional Facility/ Institutional Setting	35	19	-46%
Private Residence - Independent or Dependent	79	99	25%
SUD Residential Treatment Facility	26	22	-15%

² Data not available for clients without treatment records collected in the Salt Lake County dataset (clients coming from the Department of Corrections Treatment Resource Centers or out-of-network providers,

Medicaid and self-pay clients, or those who transition to the Patient Assistance Plan (PAP) and wish to not continue case management with the Salt Lake County Vivitrol Program).

Changes in Education

Enrolled in Education (n=140) ³	Admission of Earliest Record	Most Recent Record/Discharge	Percent Change	
Enrolled	3	7		133%
Not Enrolled	137	133		-3%

³ Data not available for clients without treatment records collected in the Salt Lake County dataset (clients coming from the Department of Corrections Treatment Resource Centers or out-of-network providers, Medicaid and self-pay clients, or those who transition to the Patient Assistance Plan (PAP) and wish to not continue case management with the Salt Lake County Vivitrol Program).

Education Outcome (n=140)	Counts	Percent of Counts
Same Level at Admission	132	94%
Increased Years of Education	8	6%

Changes in Monthly Income

Monthly Income (n=140) ⁴	Admission of Earliest Record	Most Recent Record/Discharge	Percent Change
\$0	105	89	-15%
\$1-\$1,000	14	25	79%
\$1,001 - \$2,000	15	20	33%
\$2,001 and Above	6	6	0%

⁴ Data not available for clients without treatment records collected in the Salt Lake County dataset (clients coming from the Department of Corrections Treatment Resource Centers or out-of-network providers, Medicaid and self-pay clients, or those who transition to the Patient Assistance Plan (PAP) and wish to not continue case management with the Salt Lake County Vivitrol Program).

4. Recidivism Data (New Charge Bookings Pre- and Post-Program into the Salt Lake County Jail—Analysis does not include bookings occurring in other county jails, prison, or incarceration settings outside of Utah)

Criminal justice involvement of participants: The program began with Correctional Addiction Treatment Services (CATS) program in the Jail being the sole referral source into the MAT program. Within the first year, Salt Lake County was authorized by DSAMH to open the program to eligible clients who want to

participate from the entire network of Salt Lake County Treatment providers. We continue to receive many clients from CATS, Drug Court, and the Dept of Corrections, but retention and participation rates are much lower for these populations, as compared to clients advocating to participate from an SUD provider.

Clients	All Clients with 1+ Injections	Clients with Booking History	% with Booking History	
Total Count	284	230	81%	
1 year since first injection*	120	63	53%	
2 years since first injection*	0	0	-	
3 years since first injection*	0	0	-	

^{*}open cohort, data not complete; First injections occurred 9/11/15

Clients With At Least 1 Year Since First Injection and a Booking History

	Number of Clients with a New Charge Booking	New Charge Bookings	Length of Stay for New Charge Bookings (days)
Up to 1-year prior to injection date	63	112	7,250
Up to 1-year post injection date**	23	33	1,321
Percent that did not recidivate	63%		

^{*1} extra client and 2 extra bookings removed because not released at time of data pull

Recidivism comparison group: We do not have access to benchmark data for recidivism locally. We have no relevant comparison group to analyze currently, where data is readily available.

Measures of Cost-Effectiveness

Several strategies have been employed to ensure cost-effective treatment:

- Injections offered behind the walls of the Jail continue to be provided at a 100% subsidy through the drug manufacturer.
- Currently working with Midtown Community Health Center, a Federally Qualified Health Center (FQHC) to access 340B pricing for the medication (\$649 per injection).
- Working with other Federally Qualified Health Centers that offer the 340B pricing for Vivitrol has also been explored. Salt Lake County Division of Behavioral Health Services (SLCo DBHS) has reached out to AUCH (the Association for Utah Community Health) to

^{** 2} and 3-year recidivism data not available until 2 and 3 years of data collected since injection

look for new FQHC partners. Only Fourth Street Clinic has expressed interest in offering Vivitrol treatment through their community health center. The agency has indicated that their appointment system is several months away from being capable of processing Vivitrol clients in an effective manner. SLCo DBHS continues to try to coordinate this effort.

- Also, the Odyssey House Martindale Clinic (non-FQHC offering the medication at \$1,009 per injection) has inquired about receiving FQHC or FQHC look-alike status, which would allow for 340B pricing for the medication. Odyssey House put in an application for FQHC status in early 2017 and was not approved. Odyssey House has now applied for the look-alike status, in anticipation of hearing back in the Fall of 2017.
- SLCo DBHS has assisted both Martindale and Midtown clinics in screening clients for eligibility into the Vivitrol Patient Assistance Plan (PAP).
 - At Martindale, currently 30%, but as high as 45% of the Vivitrol injections are via the Patient Assistance Program, thus reducing the cost of programming substantially. Martindale was notified by the Alkermes representative that they have the highest number of patient assistance in the nation.
- Clients are also being screened for Medicaid, which covers the full cost of the injection.
 Clients on Medicaid are often no longer case managed through SLCo DBHS because they have access to payer resource that does not require adherence to County standards, treatment engagement at a network provider, or case management through SLCo DBHS.
 This is based upon client choice (leaving the County's Program), and when selected, results in the inability for SLCo DBHS to track the clients' success, costs, or other outcomes.

6. Other Options for Reducing Costs

Salt Lake County Behavioral Health Services would defer to the State Division of Substance Abuse and Mental Health (DSAMH) regarding the usage of compounding pharmacies. DSAMH has provided insightful research into the inability to compound Naltrexone as a long-acting injectable. The following information was collected through DSAMH:

Vivitrol is a rather sophisticated dosing form of naltrexone in a long-acting formulation of polymer microspheres. The FDA approved Alkermes' PLG polymer formulation for alcohol dependence in April 2006. (The Division) is not aware of any compounding pharmacies with the technology to compound an equivalent to Vivitrol. This is a sophisticated manufacturing, rather than a compounding process.

In 2013, the Drug Quality and Security Act created a new section 503B of the Federal Food, Drug, and Cosmetic Act, which describes a new category of compounders called outsourcing

facilities (i.e. compounding pharmacies). These facilities must have state-of-the-art clean rooms and processes compliant with USP 797 standards.

For a drug product compounded by an outsourcing facility to qualify for the exemptions under 18 section 503B of the Federal Food, Drug, and Cosmetic Act, the product must not be "essentially a copy of one or more approved drug products"

Vivitrol is an FDA-approved drug product. Outsourcing facilities (i.e. compounding pharmacies) are not allowed to copy this commercially-available product.

Naltrexone is also available in a pellet formulation that is surgically implanted into the abdomen. It releases the active ingredient over a 3-6 month period. BioCorRx has exclusive rights to the naltrexone implant (https://globenewswire.com/news-release/2015/03/18/716277/10125317/en/BioCorRx-Inc-Announces-Reinstatement-of-Letter-of-Understanding-to-Acquire-Naltrexone-Implant-Formula-for-Treating-Addiction.html).

Some compounding pharmacies prepare Naltrexone in transdermal cream, oral suspension, or low-dose capsules. (The Division has) done a thorough web search of many different resources, and can find no information regarding any compounding pharmacy with the ability to compound a long-acting injectable naltrexone. (The Division) does not believe a compounded equivalent of Vivitrol is available.

7. Other Funding Options Beyond One-Time Funding

Salt Lake County applied for and was awarded funding through the State Targeted Response (STR) Grant for Opioid Treatment funding. Salt Lake County has chosen to utilize the awarded funding (approximately \$1.25M) to open two additional MAT clinics in separate State-identified opioid hotspots (Murray and West Jordan), and to increase MAT services in the downtown Salt Lake area. These clinics will provide Suboxone and Vivitrol in West Jordan, and Methadone, Suboxone and Vivitrol in Murray and Salt Lake City. They will serve a portion of the currently unmet need based on the capacity constraints of the Salt Lake County Vivitrol Program. These funds are <u>not</u> ongoing.

Additionally, the Salt Lake County Council appropriated an additional \$250k in one-time funding to cover the gap in medication costs incurred by expanding the Vivitrol Program, beyond what was funded through State appropriation.

Salt Lake County Division of Behavioral Health Services would defer to the State Division of Substance Abuse and Mental Health regarding any additional efforts made to identify sources of funding beyond the current one-time appropriation.